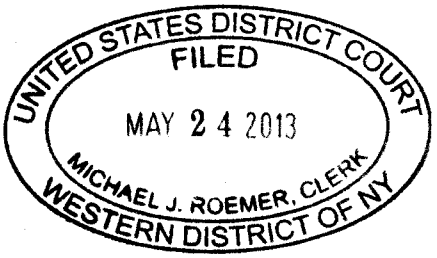

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA	:	13-CR-99A
-v-	:	**I N F O R M A T I O N**
ISTA PHARMACEUTICALS, INC.,	:	(Title 18, U.S.C. § 371) (2 Counts and Forfeiture Allegation)
Defendant.	:	

INTRODUCTORY ALLEGATIONS

The United States Attorney Charges That At All Times Relevant To This Information:

1. Defendant ISTA PHARMACEUTICALS, INC. ("ISTA") was a Delaware corporation with its principal place of business located in Irvine, California.

2. Defendant ISTA was engaged in the licensing, development, promotion, and sale of pharmaceutical drugs intended for human use, including the drug Xibrom.

3. Defendant ISTA promoted and sold Xibrom throughout the United States, including in the Western District of New York. Xibrom was prescribed by physicians and dispensed by pharmacies throughout the United States, including in the Western District of New York.

4. Xibrom was a new drug and a prescription drug within the meaning of the Federal Food, Drug, and Cosmetic Act ("FDCA"), which, among other things, governed the interstate distribution of drugs for human use, as codified in 21 U.S.C. §§ 301, *et seq.* The FDCA and its implementing regulations prohibited the distribution of any new drug in interstate commerce until the sponsor or manufacturer of that new drug had received approval from the United States Food and Drug Administration ("FDA"), based on an intensive application and review process. 21 U.S.C. § 355.

5. The FDCA required that the sponsor of a new drug submit a New Drug Application to the FDA, which identified all of the uses of the drug intended by that sponsor, together with the proposed labeling for those uses and data, generated in well-controlled clinical trials, that demonstrated to the FDA's satisfaction that the drug would be safe and effective for those intended uses. 21 U.S.C. §§ 331(d) and 355(b).

6. Until the FDA approved the New Drug Application, including the proposed labeling for the drug, and found sufficient evidence of the drug's safety and efficacy for the uses intended by the sponsor, the FDCA prohibited the sponsor

from promoting or marketing its drug. 21 U.S.C. § 355(a). Uses not approved by the FDA, and not included in the drug's approved labeling, were known as "unapproved uses" or "off-label uses."

7. The sponsor could not label or promote the drug for any new intended use without the prior approval of the FDA. The sponsor was first required to submit to the FDA for approval each additional proposed use, together with evidence, in the form of well-controlled clinical studies, sufficient to demonstrate that the drug was safe and effective for each additional proposed therapeutic use.

8. Under the FDCA, a drug was "misbranded" if its labeling did not contain "adequate directions for use." 21 U.S.C. § 352(f)(1). "Adequate directions for use" meant directions under which a layperson could use a drug safely and effectively for the purposes for which it was intended. 21 C.F.R. § 201.5. A prescription drug, by definition, could not bear adequate directions for use by a layperson, but an FDA-approved prescription drug, bearing the FDA-approved labeling, could be exempt from the adequate directions for use requirement if it was sold for an FDA-approved use. A prescription drug that was marketed for unapproved and off-label uses did not

qualify for this exemption and therefore was misbranded. 21 C.F.R. § 201.100.

9. Labeling included any written, printed, or graphic matter that accompanied a drug, and further included materials disseminated by or on behalf of a drug manufacturer or distributor that were descriptive of a drug.

FDA Approval and Regulatory Action

10. On May 24, 2004, defendant ISTA submitted a New Drug Application seeking approval of a drug called Xibrom (also known by the chemical name bromfenac) ophthalmic solution for the treatment of postoperative inflammation and for the reduction of eye pain and photophobia in patients who have undergone cataract extraction.

11. On March 24, 2005, the FDA approved Xibrom for the treatment of postoperative inflammation in patients who have undergone cataract extraction. The approved product label stated that dosage was one drop of Xibrom to the affected eye(s) two times daily beginning 24 hours after cataract surgery and continuing through the first 2 weeks of postoperative period. The approved product label included the following precautions:

"All topical nonsteroidal anti-inflammatory drugs (NSAIDs) may slow or delay healing.... In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs and should be closely monitored for corneal health."

12. The initial retail trade package of Xibrom approved by FDA was 5.0mL of the Xibrom solution product.

13. The initial physician's sample size of Xibrom approved by FDA was 2.5mL of the Xibrom solution product.

14. On July 14, 2005, defendant ISTA submitted a supplemental New Drug Application for the use of Xibrom for the reduction of ocular pain in patients who have undergone cataract extraction.

15. On January 27, 2006, the FDA approved Xibrom for the reduction of ocular pain in patients who have undergone cataract extraction. The approved product label contained the same dosage and precautions as approved on March 24, 2005.

16. On or around February 14, 2006, defendant ISTA submitted a supplemental New Drug Application seeking approval of 1.0mL physician's sample size of the Xibrom solution product.

17. On or around March 1, 2006, defendant ISTA launched a retail trade package of 2.5mL of the Xibrom solution product.

18. On June 13, 2006, the FDA approved defendant ISTA's supplemental New Drug Application for a 1.0mL physician's sample size of the Xibrom solution product.

19. On December 4, 2008, defendant ISTA submitted a supplemental New Drug Application for the use of Xibrom for the treatment of ocular inflammation and pain associated with refractive surgeries.

20. On May 4, 2010, the FDA denied defendant ISTA's supplemental New Drug Application to extend the use of Xibrom for the treatment of ocular inflammation and pain associated with refractive surgeries. FDA informed ISTA that: "The submitted references do not support the extrapolation of clinical studies using a non-steroidal anti-inflammatory in cataract surgery to postoperative inflammation and pain in all ocular surgeries.... In summary, adequate and well controlled

studies have not been conducted with bromfenac ophthalmic solution which demonstrate efficacy in the treatment of ocular inflammation and pain associated with refractive surgeries."

21. At no time did the FDA approve Xibrom for any of the following uses: the treatment of ocular inflammation or pain associated with refractive surgeries; the treatment of ocular inflammation or pain associated with glaucoma surgery; or the prevention or treatment of cystoid macular edema.

Submissions to FDA

22. On or about November 16, 2005, defendant ISTA contacted FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") asserting that [Company A]'s promotion of [Drug A] was in violation of the law. ISTA stated that [Company A] "is engaging in a significant nationwide campaign to promote [Drug A] for a variety of indications for which the drug is not approved by the FDA." Specifically, ISTA asserted that [Company A] was promoting [Drug A] for use in treatment of CME, PRK and Lasik. ISTA noted that "depicting the retina ... for [Drug A] implies that the drug is approved for use in posterior segment eye diseases such as cystoid macular edema (CME).... However, no posterior chamber indications are approved for [Drug

A]." ISTA also asserted that [Company A] used an "unrestricted educational grant" to promote [Drug A] for refractive patients, which was also an unapproved use. ISTA concluded: "[Company A] has engaged, and is continuing to engage, in a widespread and substantial marketing campaign to promote their product [Drug A] for various indications for non-cataract surgery related, posterior chamber conditions, none of which is approved by the FDA."

23. On or about February 14, 2006, defendant ISTA contacted FDA's DDMAC asserting that a sales aid by [Company A] was in violation of the law. ISTA stated that the headline and graphic used by [Company A] "show a clear intent by [Company A] to promote [Drug A] for treatment of diseases of the posterior chamber and retina." ISTA concluded: "the mere fact the sales aide [sic] discusses [Drug A]'s effectiveness in the vitreous humor violates the new drug provisions since the product is not approved for any posterior chamber indication."

24. On or about July 10, 2006, defendant ISTA contacted FDA's DDMAC asserting that an advertisement on [Company A]'s website "continues [Company A]'s ongoing campaign ... to demonstrate that [Drug A] penetrates the vitreous and is efficacious for retinal and other posterior chamber

indications." ISTA asserted that these uses were not within [Drug A]'s approved label, and urged the FDA "to take immediate action to compel [Company A] to cease its violative promotional activities."

25. On or about October 26, 2006, defendant ISTA contacted FDA's DDMAC and identified a new [Company A] advertisement "whose single purpose is to tout the use of [Drug A] for cystoid macular edema, a condition of the retina for which [Drug A] is not approved." ISTA considered the advertisement as "touting off label uses of [Drug A]" and urged the FDA to act.

26. On or about November 1, 2006, defendant ISTA contacted FDA's DDMAC asserting that a journal advertisement by [Company B] with respect to its NSAID medication, [Drug B], was misleading. ISTA wrote that [Company B] was promoting [Drug B] for "ocular surgery" when the drug was only approved for use following a specific type of surgery. ISTA asserted that the advertisement was "misleading" because it "broadens the scope of the indication for [Drug B]" and implied that the drug was effective for "any and all ocular surgeries" while its approved indication was "only a small subset." ISTA urged the FDA to investigate and take the appropriate action.

27. On or about December 14, 2006, defendant ISTA contacted FDA's DDMAC complaining about an "equally violative journal ad." ISTA asserted "[a]lthough [Company B] is using human data to support its claim, the human data studied was in patients undergoing [different treatments]. [Drug B] is not approved for this use. Therefore, the advertisement is false and misleading as it presents efficacy data and comparison data for an off-label use." ISTA also asserted that the advertisement was false and misleading because the advertisement presented "dosage and administration not contained in the FDA approved package insert." According to ISTA, the advertisement recommended use of [Drug B] pre-operatively, while the dosage and administration section of the approved product label only referenced postoperative use.

Xibrom and the Medicaid Program

28. Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.*, established a program to enable the states to furnish medical assistance to certain categories of persons whose income and resources were insufficient to meet the costs of necessary medical services. Commonly called Medicaid, the program was administered by the states, but was funded jointly by the federal and state governments.

29. To participate in the Medicaid program, a state was required to develop a plan that was approved by the Secretary of Health and Human Services as meeting federal requirements. The state paid qualified providers for furnishing necessary services covered by the state plan to individuals who were eligible for medical assistance. The federal government contributed a portion of the costs that each participating state incurred in purchasing items and services from qualified providers on behalf of eligible persons. The state bore the remainder of the costs.

30. State Medicaid programs were "federal health care programs" within the meaning of 18 U.S.C. § 24, in that they were public plans affecting commerce under which medical benefits, items and services were provided to individuals under the plans.

31. The federal government contributed to the costs of prescriptions for persons who were Medicaid beneficiaries, including but not limited to persons who needed surgery to correct cataracts under the state Medicaid programs.

32. Federal health care programs paid for Xibrom prescriptions nationwide.

COUNT I

(Conspiracy to Violate the Food, Drug, and Cosmetic Act)

33. The Introductory Allegations are hereby re-alleged and incorporated by reference as if fully set forth herein.

34. Beginning in or around September 2005, and continuing thereafter until in or around November 2010, the exact dates being unknown to the United States Attorney, within the Western District of New York and elsewhere, the defendant **ISTA PHARMACEUTICALS, INC.** and others known and unknown to the United States Attorney, knowingly and willfully combined, conspired, and agreed, to commit an offense against the United States, to wit, 21 U.S.C. §§ 331(a), 333(a)(2), by introducing and delivering for introduction into interstate commerce, and causing to be introduced and delivered for introduction into interstate commerce, with intent to defraud and mislead, misbranded drugs consisting of Xibrom, which drugs were misbranded within the meaning of Title 21, United States Code, Section 352(f)(1), in that the drugs lacked adequate direction for use for each of its intended uses.

Purpose of the Conspiracy

35. It was the purpose of this conspiracy that defendant ISTA and others known and unknown to the United States Attorney introduced and delivered for introduction, into interstate commerce, and caused to be introduced and delivered for introduction into interstate commerce, with intent to defraud and mislead, misbranded drugs to: increase the sale of Xibrom; increase revenues for the defendant; inflate profits for the defendant; inflate the stock value of defendant; increase compensation, other remuneration, and stock value for others known and unknown to the United States Attorney; and inflate the sale price of defendant.

Means and Manner of the Conspiracy

36. It was a part of the conspiracy that defendant ISTA and others known and unknown to the United States Attorney devised and executed a plan to create new intended uses for Xibrom other than its FDA approved uses.

37. It was further part of the conspiracy that defendant ISTA and others known and unknown to the United States Attorney devised and executed a plan to promote Xibrom to physicians

throughout the United States, including physicians in the Western District of New York, for uses other than its FDA approved uses.

38. It was a further part of the conspiracy that defendant ISTA and others known and unknown to the United States Attorney devised and executed a plan to pay for and distribute post-operative instruction sheets to physicians for uses of Xibrom that were not approved by the FDA as safe and effective.

39. It was a further part of the conspiracy that defendant ISTA and others known and unknown to the United States Attorney devised and executed a plan to sponsor and actively participate in providing continuing medical education programs to promote Xibrom for uses that were not approved by the FDA as safe and effective.

Overt Acts

In furtherance of this conspiracy, the defendant ISTA and others known and unknown to the United States Attorney engaged in the following overt acts in the Western District of New York and elsewhere:

40. Beginning in or around September 2005 and continuing until in or around November 2010, some ISTA employees, with the knowledge and at the direction of some members of ISTA's management team, promoted Xibrom to physicians throughout the United States, including physicians in the Western District of New York, for uses other than its FDA approved uses. The new intended uses for which Xibrom was promoted by certain ISTA employees included: post Lasik surgery; post Photorefractive Keratectomy ("PRK") surgery; post glaucoma surgery; post Selective Laser Trabeculoplasty ("SLT") surgery; and following surgeries performed with YAG lasers. Xibrom was also promoted by certain ISTA employees for treatment and prevention of conditions associated with the retina (i.e., the back of the eye), such as cystoid macular edema. Some ISTA employees promoted Xibrom for these non-FDA approved uses based on directions and financial incentives from ISTA.

41. In or around November 2005, some of defendant ISTA's employees discussed the introduction into the market of a smaller size of Xibrom - 2.5mL - in order to broaden sales of Xibrom for short term use, such as after Lasik surgery. Use of Xibrom after Lasik surgery is a use not approved by FDA.

42. In or around December 2005, an ISTA employee prepared a presentation including a "Trade Plan" for Xibrom that stated that the "introduction of a 2.5mL provides opportunity to pursue 'short-term' treatments (i.e., LASIK) = 50% of the Xibrom market opportunity."

43. Beginning in or around February 2006, defendant ISTA distributed continuing medical educational materials to physicians throughout the United States, including physicians in the Western District of New York. In some cases, ISTA employees used some of these materials to promote Xibrom for uses not approved by FDA. Certain ISTA employees, with the knowledge and at the direction of ISTA, also sponsored and actively participated in providing continuing medical education programs to promote Xibrom for uses that were not approved by the FDA as safe and effective.

44. On or about April 28, 2006, one of defendant ISTA's employees informed a pharmaceutical industry analyst that Xibrom's smaller size "is short term use (post-Epi Lasik surgery)" and the original 5.0mL size package of Xibrom was used for "cataracts and CME [cystoid macular edema]." The use of

Xibrom for post-Epi-Lasik surgery and for cystoid macular edema was not approved by FDA.

45. On or about August 7, 2006, a presentation for defendant ISTA's Sales and Marketing Leadership Team noted, referring to cystoid macular edema: "If you can treat it, you can prevent it!" The presentation concluded: "Tying it all together in a promotional message - The New Sales Aid.... Quickly knocking out prostaglandins in the anterior chamber helps resolve inflammation and prevent CME. If you can effectively treat CME, you can prevent CME." However, the presentation did not include an examination or results explicitly related to the effectiveness of Xibrom to prevent cystoid macular edema.

46. On or about October 8, 2006, one of defendant ISTA's employees e-mailed other employees asking them to invite physicians to listen to a lunch teleconference in which a speaker hired by ISTA "will cover many topics concerning Xibrom including surgical and off-label uses. Let's make sure we can get maximum impact with this program and target our physicians wisely for this excellent opportunity."

47. Beginning in or around December 2006, defendant ISTA paid for and distributed to physicians post-operative instruction sheets for uses of Xibrom not approved by FDA, including use after Lasik, PRK, and Pterygium surgeries.

48. On or about January 5, 2007, one of defendant ISTA's employees stated that he and another employee "closed a deal with [Physician Laser Practice] and 7 individual Centers that will have the centers converting to Xibrom for PRK and Lasik. This became effective January 1, 2007. Estimated 650+ new prescriptions per month for the various centers."

49. On or about February 16, 2007, one of defendant ISTA's employees e-mailed other employees an attachment "created to help the TM's [Sales Representatives] understand the 'real' opportunity for Xibrom on a daily basis." The attachment identified a significant number of uses for Xibrom not approved by FDA, including use after Lasik, PRK, glaucoma, SLT, and YAG surgeries, and use in connection with conditions associated with the retina, such as cystoid macular edema.

50. On or about February 27, 2007, some of defendant ISTA's employees attended a "Plan of Action" meeting and were instructed to promote Xibrom for a number of uses not approved

by FDA, including use after refractive surgery such as Lasik, PRK, glaucoma, SLT, and YAG surgeries, and use in connection with conditions associated with the retina, such as cystoid macular edema.

51. On or about February 27, 2007, one of defendant ISTA's employees presented a slide deck titled "Pre-Call Planning & Product Positioning for Sales Impact" to other employees. The presentation identified a number of uses for Xibrom not approved by FDA, such as refractive, cystoid macular edema, allergy, and abrasions. These unapproved uses and others were termed "Pots of Gold." The presentation ended with a series of slides which asked "What's in it for me?" and answered "Financial Rewards, Recognition, Stock Growth, Job Satisfaction, Company Growth, [and] Promotion?"

52. On or about August 6, 2007, one of defendant ISTA's employees e-mailed other employees and stated that "I would like to see us sign a contract with [Physician Laser Practice] for their Refractive Business." One employee responded "Good idea regarding [Physician Laser Practice]." Another employee responded "On the [Physician Laser Practice] contract[.] Go for it. What's in your way. You got ball."

53. On or about September 14, 2007, one of defendant ISTA's employees e-mailed other ISTA employees and stated: "The obvious challenge is that most of [Physician Laser Practice] is about Lasik. Some PRK. We are not indicated for Lasik and there is very little pain or inflammation."

54. In or around October 2007, defendant ISTA agreed to give $5,000 to sponsor a golf outing for physicians affiliated with [Physician Laser Practice], an organization that primarily focused on laser eye surgery. On or around October 25, 2007, defendant ISTA's general ledger included an entry of $5,000 for a "US EDUCATIONAL GRANT [Physician Laser Practice] LASER EYE." This money was used to fund the golf outing.

55. On or about November 12, 2007, one of defendant ISTA's employees e-mailed other employees and informed them that the cystoid macular edema "study was a physician initiated trial.... We do not plan to pursue the indication at this point...."

56. On or about January 11, 2008, one of defendant ISTA's employees e-mailed other employees and stated: "Beginning in February, [Physician Laser Practice] in Richmond will be adding Xibrom into all Lasik Procedures. This is a satellite office of [Physician A]. This will equate to 80 plus Rxes on a monthly

basis for my territory, the district and the region. All of these Rxes will be written for the 5 ml bottle with a refill." A senior executive of ISTA responded "you amaze me (in a good way)!!! Congratulations."

57. On or about January 15, 2008, one of defendant ISTA's employees e-mailed other employees and informed them that three doctors "have all updated their Refractive Regimens [sic] to include Xibrom. Please see attached instruction sheet.... Who will be the next to take advantage of this unique selling opportunity?"

58. On or about January 15, 2008, some of defendant ISTA's employees attended a "Plan of Action" meeting and were instructed to "close for something on every call." Included as examples of uses to close on were post-Lasik, glaucoma, SLT, and PRK surgeries, none of which were FDA-approved uses.

59. On or about January 15, 2008, one of defendant ISTA's employees e-mailed another employee and described how, based upon training the employee received from a manager, the employee convinced two ophthalmologists to prescribe Xibrom for three days pre-operatively and up to six weeks post-operatively to prevent cystoid macular edema, a use not approved by FDA.

60. On or about January 15, 2008, one of defendant ISTA's employees e-mailed other employees and informed the employees with a laser eye center in their district that they "should have visited these accounts and provided a status report to your [district manager] by that day. This report should include details and a profile of the OD's and MD's involved. What the Center is currently using and why and of course your goals going forward plus any needs from me...." Some ISTA employees were told by management not to memorialize in writing certain interactions with physicians regarding unapproved new uses, and not to leave certain printed materials in physicians' offices relating to unapproved new uses. These instructions were given in order to avoid having their conduct relating to unapproved new uses being detected by others; in other words, with the intent to defraud.

All in violation of Title 18, United States Code, Section 371, and Title 21, United States Code, Sections 331(a), 352(f)(1) and 333(a)(2) .

COUNT II

(Conspiracy to Violate the Federal Anti-Kickback Statute)

The United States Attorney Further Charges That At All Times Relevant To This Information:

61. The Introductory Allegations, and the allegations set forth in Count I of this Indictment, are hereby re-alleged and incorporated by reference as though fully set herein.

62. Beginning in or around December 2005, and continuing thereafter until in or around November 2008, the exact dates being unknown to the United States Attorney, in the Western District of New York and elsewhere, defendant ISTA and others known and unknown to the United States Attorney, knowingly and willfully combined, conspired, and agreed to commit an offense against the United States, to wit, 42 U.S.C. § 1320a-7b(b)(2)(A), by knowingly and willfully offering and paying remuneration, directly and indirectly, overtly and covertly, in cash and in kind, to physicians to induce them to refer individuals, including Medicaid patients, to pharmacies for the furnishing of the drug Xibrom, for which payments were made in whole and in part under state Medicaid programs.

Purpose of the Conspiracy

63. It was the purpose of this conspiracy that defendant ISTA and others known and unknown to the United States Attorney induced physicians with free goods and other remuneration in order to: increase the sale of Xibrom; increase revenues for the defendant; inflate profits for the defendant; inflate the stock value of defendant; increase compensation, other remuneration, and stock value for others known and unknown to the United States Attorney; and inflate the sale price of defendant.

Means and Manner of the Conspiracy

64. It was a part of the conspiracy that defendant ISTA and others known and unknown to the United States Attorney devised and executed a plan to induce certain unnamed physicians to refer individuals to pharmacies for the dispensing of the drug Xibrom by offering and providing these physicians with free Vitrase, another ISTA product.

65. It was a further part of the conspiracy that defendant ISTA and others known and unknown to the United States Attorney devised and executed a plan With the intent to induce certain unnamed physicians to refer individuals to pharmacies for the

dispensing of the drug Xibrom by making a substantial monetary payment to a non-profit entity associated with one of these physicians, which ISTA believed to be a personal benefit to that physician, and providing other remuneration to other physicians.

66. It was a further part of the conspiracy that defendant ISTA and others known and unknown to the United States Attorney devised and executed a plan to induce certain unnamed physicians to refer individuals to pharmacies for the dispensing of the drug Xibrom by offering such physicians paid consulting or speaker arrangements, pursuant to which such physicians were compensated in excess of fair market value of services received.

67. It was a further part of the conspiracy that defendant ISTA and others known and unknown to the United States Attorney devised and executed a plan to induce certain unnamed physicians to refer individuals to pharmacies for the dispensing of the drug Xibrom by inviting such physicians to participate in certain advisory board meetings which were intended to be marketing opportunities and provided such physicians remuneration in excess of fair market value of services received.

Overt Acts

In furtherance of this conspiracy, and to effect the objects thereof, defendant ISTA and others known and unknown to the United States Attorney engaged in the following overt acts, among others, in the Western District of New York and elsewhere:

68. On or about September 21, 2006, one of defendant ISTA's employees e-mailed another employee and included an attachment noting that one way of "Growing the Business" was to use Vitrase as "Leverage for Xibrom."

69. On or about November 21, 2006, one of defendant ISTA's employees sent an e-mail with an attachment that included a "Proposal to leverage Vitrase for Xibrom" to other ISTA employees. The proposal "outlines the financial justification to leverage Vitrase in order to gain a significant amount of Xibrom business" from [Physician B]'s practice. In the first scenario, ISTA proposed giving free Vitrase to doctors in exchange for prescriptions of Xibrom. In the second scenario, ISTA proposed offering Vitrase at a discount if the doctor's practice "convert[ed] all NSAID Rxs to Xibrom." According to the proposal, "Scenario 2 is best and what [we] want to sell them. However, even worst case scenario 1 is a BIG WIN for ISTA!"

70. On or about February 6, 2007, defendant ISTA distributed free Vitrase to [Physician B]'s practice.

71. Between on or about March 5, 2007, and on or about September 10, 2007, defendant ISTA distributed 17 shipments of free Vitrase to [Physician B]'s practice.

72. On or about January 22, 2007, one of defendant ISTA's employees e-mailed other ISTA employees proposing to discount Vitrase for more prescriptions of Xibrom from [Physician's Practice]: "Net Net Discount Vitrase by about $5500.00 to make $35,000 on Xibrom. I'm okay with this. Your thoughts?" The recipient of this e-mail responded that same day: "Looks good to me, if it does to you!"

73. On or about January 31, 2007, defendant ISTA distributed six vials of free Vitrase to [Physician's Practice].

74. Between in or around January 2007 and in or around September 2007, defendant ISTA shipped more than 3,500 vials of free Vitrase to physician practices throughout the United States to induce such physicians to refer individuals to pharmacies for the dispensing of the drug Xibrom.

75. On or about October 3, 2007, one of defendant ISTA's executives e-mailed other employees informing them of a monetary payment to sponsor an event of a non-profit group associated with [Physician C], and stating: "Lets [sic] make this work for us." One of ISTA's employees e-mailed another employee and stated the belief that "the cost of doing business with [the physician] to get all the nsaid business" included, among other things, "$50,000 for a sponsored meeting [the physician] is personally connected to[.]"

76. On or about January 9, 2008, defendant ISTA paid $50,000 to sponsor an event of a non-profit group associated with [Physician C] with the intent to induce such physician to refer individuals to pharmacies for the dispensing of the drug Xibrom.

77. Between in or around June 2007 and in or around November 2008, defendant ISTA provided remuneration in the form of a golf outing and a wine tasting reception to physicians in order to induce such physicians to refer individuals to pharmacies for the dispensing of the drug Xibrom.

78. Beginning in or around December 2005, defendant ISTA provided $20,000 in purported research grants, and additional

remuneration to [Physician D] with the intent to induce [Physician D] to refer individuals to pharmacies for the dispensing of the drug Xibrom. For example, as a result of ISTA's efforts to create speaking opportunities for him, [Physician D], in the words of an ISTA employee, "committed ... to switching all of his cataract patients ... to Xibrom." In the aggregate, the compensation to [Physician D] was in excess of fair market value for services received.

79. In or around September 2005, an ISTA employee emailed a manager, "urgently requesting" that his "#1 and #2 NSAID prescribers, [Physician E and Physician F]," be invited to participate in an ISTA advisory board panel. The ISTA employee explained that it was "a critical time in converting their nsaid business, and I think both doctors see participating with ISTA on a higher level as part of the deal." The ISTA manager responded "DONE!"

80. In or around February 2007, one of defendant ISTA's employees wrote a "Strategic Plan for 2007" for his/her Region which identified the following strategy: "We continue to seek ways to Maximize our Opportunities by insuring the greatest ROI [return on investment]. History has proven that Advisors Meetings are an excellent program that supports our sales

efforts. I expect that this most recent Advisors Meeting in NYC will exceed our expectations in market share growth throughout 2007."

81. In early 2008, defendant ISTA invited [Physician G], who practiced in the Western District of New York, to attend a market research meeting in Florida. [Physician G] attended the meeting, which ISTA intended to be a marketing opportunity and provided the physician remuneration in excess of fair market value of services received.

82. On or about April 25, 2007, one of defendant ISTA's employees e-mailed another ISTA employee and stated: "The NYC ad board strikes again!" The sender proceeded to detail how a physician who attended an Advisory Board meeting agreed to switch his prescriptions to Xibrom and further stated: "Once again, a large Xibrom conversion on the heels of the NYC advisory board."

All in violation of Title 18, United States Code, Section 371, and Title 42, United States Code, Section 1320A-7B(b)(2)(B).

FORFEITURE ALLEGATION

The United States Attorney Alleges That:

As a result of its conviction on Count I of this Information, the defendant ISTA PHARMACEUTICALS, INC. shall forfeit to the United States all right, title, and interest in property, real or personal, which constitutes or is derived from proceeds traceable to an offense of conviction including the following:

PROPERTY

A quantity of the drug, Xibrom, that it misbranded and distributed in interstate commerce.

SUBSTITUTE ASSETS

If any of the property described above as a result of any act or omission if the defendant:

1. cannot be located upon the exercise of due diligence;
2. has been transferred or sold to, or deposited with, a third person;
3. has been placed beyond the jurisdiction of the Court;
4. has been substantially diminished in value; or
5. has been commingled with other property that cannot be subdivided without difficulty;

the court shall order the forfeiture of any other property of the defendant of $1,850,000.00 (One million, eight hundred and fifty thousand dollars).

All pursuant to the provision of Title 28, United States Code, Section 2461(c), and Title 21, United States Code, Sections 334 and 853(p).

Dated: Buffalo, New York, May 23, 2013

WILLIAM J. HOCHUL, JR.
United States Attorney

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